

Attorney Docket No.: **06244-00002 (CHM-0003)**
Inventors: **Hulkower et al.**
Serial No.: **10/775,780**
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REMARKS

Claims 137-153 are pending in this application. Claims 143-147 have been withdrawn from consideration and canceled. Claims 137-142 and 148-153 have been rejected. No new matter has been added. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. §121

Claims 137-153 have been subjected to a Restriction Requirement under 35 U.S.C. §121 by the Examiner in this case. The Examiner suggests that restriction of the present invention into the following groups is required:

Group I, claims 137-142 and 148-153, drawn to devices and kits, classified in class 435/975, for example; and

Group II, claims 143-147, drawn to a method of detection, classified in class 436/55, for example.

It is suggested that the inventions are related as products and processes of use; however, they are distinct because, e.g., the products can be used in materially different process such as photodynamic processes. Applicants' election of claim 137-141 with traverse is acknowledged, but the restriction requirement placing the claims into Groups I and II has been deemed proper and made final. Claims 143-147 have been withdrawn from further consideration. Accordingly, Applicants are canceling claims 143-147 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

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II. Rejection of Claims Under 35 U.S.C. §102

Claims 137-142 and 148-153 have been rejected under 35 U.S.C. 102(b) as being anticipated by Humphries et al. (U.S. Patent No. 4,849,330). It is suggested that Humphries et al. describe a device comprising an analyte-specific compound (col. 8, line 47), an analyte (col. 8, lines 49-50), a detectable compound (col. 9, line 41), a porphyrin dye (col. 7, lines 53-54), an enzyme conjugated to the analyte-specific compound (col. 10, lines 56-57), a substrate of the enzyme (col. 10, line 51), a conjugate comprising an enzyme and a non-analyte-specific compounds (col. 9, line 26-29), a capture analyte-specific compound (col. 11, line 12), a tracer comprising an analyte molecule bound to an enzyme (col. 9, lines 26-29), a receptor molecule (col. 8, line 47) and a sample (col. 9, line 28). Applicants respectfully traverse this rejection.

While Humphries et al. describe the use of cytochrome c and cytochrome b₂, this reference does not teach or suggest the use of a porphyrin dye molecule which binds a detectable compound. Stryer ((1988) In: Biochemistry, 3rd Ed., W.H. Freeman and Company, New York, pp. 407-408) enclosed herewith teaches that the overall structure of cytochrome c is characterized as a one-residue thick shell surrounding the heme prosthetic group which is an iron atom embedded in a porphyrin ring system. As such, the heme group is excluded from interacting with molecules other than the cytochrome protein component. Conversely, a dye is generally accepted as a colorant that chemically binds to a substrate (see Lewis (1997) In: Hawley's Condensed Chemical Dictionary, 13th Ed., Van Nostrand Reinhold, New York, pg. 289) enclosed herewith. In this regard, the instant invention discloses porphyrin dyes

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for binding to a detectable compound thereby producing a detectable response. Accordingly, the cytochrome c and cytochrome b₂ of Humphries et al. do not anticipate the porphyrin dyes of the instant invention. Thus, because Humphries et al. fail to teach each and every element of the instant claims, this reference does not anticipate the instant invention in accord with the requirements set forth in MPEP §2131. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Double Patenting

Claims 137-142 and 148-153 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 40 of U.S. Patent No. 6,495,102 in view of Humphries et al. (U.S. Patent No. 4,849,330). The Examiner suggests that U.S. Patent No. 6,495,102 claims a device comprising at least one porphyrin dye, but fails to claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample. It is suggested that because Humphries et al. describe these components it would have been obvious to one of ordinary skill in the art to modify the nose, as recited in claims 1 and 40 of U.S. Patent No. 6,495,102, by inserting various immunoassay components in the nose, as Humphries et al. discovered a device providing "specific

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interactions" for detecting the presence of "specific components" in complex mixtures, such as urine.

Claims 137-142 and 148-153 have also been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 26 of copending Application No. 10/278,421 in view of Humphries et al., or alternatively, claim 1 and 21 of copending Application No. 10/279,788 in view of Humphries et al. The Examiner suggests that Application Nos. 10/278,421 and 10/279,788 claim a device comprising at least one porphyrin dye, but fail to claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample. It is suggested that because Humphries et al. describe these components it would have been obvious to one of ordinary skill in the art to modify the tongue, as recited in claims 1 and 26 of Application No. 10/278,421, or alternatively, claims 1 and 21 of Application No. 10/279,788, by placing various immunoassay components on the tongue, as Humphries et al. discovered a device providing "specific interactions" for detecting the presence of "specific components" in complex mixtures, such as urine.

Applicants respectfully traverse these rejections.

Since the analysis employed in an obvious-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied

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for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. MPEP 804.

As such, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Moreover, the courts have held that claims cannot be rendered obvious when the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352. MPEP 2143.01.

The devices claimed in U.S. Patent No. 6,495,102 and U.S. Patent Application Nos. 10/278,421 and 10/279,788 operate by direct binding of porphyrin dyes to distinct analytes in solution or in a solid such that upon binding to the analytes, the porphyrin dyes change color. In contrast, the porphyrin dyes of the instant device are employed to indirectly detect the presence of a select analyte via an analyte-specific compound that binds to the select analyte. Accordingly, the proposed modification or combination of prior art would require a substantial reconstruction and redesign of the devices of U.S. Patent No. 6,495,102 and U.S. Patent Application Nos. 10/278,421 and 10/279,788, as well as a change in the basic principle under which the devices were designed to operate, to employ analyte-specific compounds to indirectly detect the presence of a select analyte. Thus, the instant device is not obvious in view of U.S.

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Patent No. 6,495,102 and U.S. Patent Application Nos. 10/278,421 and 10/279,788. It is therefore respectfully requested that the obvious-type double patenting rejections be reconsidered and withdrawn.

IV. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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